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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,884	03/12/2004	Viswanathan Srinivasan	P24615	4898

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER	
SASAN, ARADHANA	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
10/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/798,884	SRINIVASAN ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21, 23-52, 64-68, 70-78, 80-87, 92-96, and 99-116* is/are pending in the application.

4a) Of the above claim(s) *64-68,70 and 71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 23-52, 72-78, 80-87, 92-96, and 99-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 07/31/2007 are acknowledged.

2. Claims 22, 53-63, 69, 79, 88-91, 97-98 were cancelled.

3. Claims 64-68, and 70-71 were withdrawn.

4. Claims 47, 78 and 81 were amended and new claims 99-116 were added.

5. Claims 1-21, 23-52, 72-78, 80-87, 92-96, and 99-116 are included in the prosecution.

Response to Arguments

Objection to Declaration

6. Applicant's submission of a declaration of better print quality is acknowledged. The objection to the declaration is withdrawn.

Objection to Specification

7. Applicant's amendment of the specification by capitalizing trademarks is acknowledged. The objection to the specification is withdrawn.

Objection to Claim 78

8. Applicant's arguments, see Page 70, filed 07/31/2007, with respect to the objection to claim 78 have been fully considered but are not persuasive because the phrase "at least one of" is unclear. The objection of 07/31/2007 is maintained.

Rejection of claims 1-3, 18-21, 78-80, and 92-96 under 35 USC § 103(a)

9. Applicant's arguments, see Page 70, filed 07/31/2007, with respect to the rejection of claims 1-3, 18-21, 78-80, and 92-96 under 35 USC § 103(a) as being

unpatentable over Fanara et al. (US 6,699,502) have been fully considered but are not persuasive.

Applicant argues that Fanara is primarily concerned with pharmaceutical compositions for the controlled release of active substances, not with the simultaneous administration of different active substances. However, Fanara discloses "pharmaceutical compositions which can be administered orally, allowing the controlled release of pharmaceutically active substances such that a therapeutic effect is observed over fairly long periods, for example in only one or even two daily doses" (Col. 3, lines 22-27). Since the same or a second active substance are disclosed in the pharmaceutical compositions, it is obvious that the therapeutic effect from the controlled release of the actives would be the result of the administration of the pharmaceutical composition.

Applicant argues that Fanara does not teach a dosage form which provides a plasma concentration within a therapeutic range of a first active substance and a plasma concentration within a therapeutic range of a second active substance over similar or substantially coextensive periods of time. Applicant argues that no written evidence was provided which shows that differences in release rates of different active substances from a single dosage form result in plasma concentrations in a therapeutic range of two active substances which are present in the single dosage form over similar or substantially coextensive periods of time. Since Fanara teaches a composition "where an active substance is released immediately and another active substance is released gradually, this makes it possible to obtain combined therapeutic effects by

means of two active substances having very different pharmacokinetic profiles" (Col. 2, lines 46-50). It would be obvious to one skilled in the art that with the varying release profiles of the different actives, the "combined therapeutic effects" would only be accomplished if the plasma concentrations of the actives were within or "substantially coextensive" with the therapeutically effective range of the two actives.

Applicant argues that it is only with hindsight that a conclusion of plasma concentrations of the two active substances that are in a therapeutic range over similar or substantially coextensive periods of time can be made and that the term "pharmacokinetic profile" encompasses a wide range of properties of a drug. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore, the rejection of 05/25/07 is maintained.

Rejection of claims 4-7, 15-17, 23-29, 30-36, 38-44, 47, 49-52, 72-77, 81-87, and 97-98 under 35 USC § 103(a)

10. Applicant's arguments, see Page 74, filed 07/31/2007, with respect to the rejection of claims 4-7, 15-17, 23-29, 30-36, 38-44, 47, 49-52, 72-77, 81-87, and 97-98 under 35 USC § 103(a) as being unpatentable over Fanara et al. (US 6,699,502) in view of Jaeger (US 3,914,425) have been fully considered but are not persuasive.

Applicant argues that neither Jaeger nor Findlay renders it obvious to provide a dosage form, which comprises two different active substances and provides similar or substantially coextensive periods of therapeutic activity of these two different active substances. Applicant argues that the disclosure of Jaeger in combination with that of Fanara does not render obvious the subject matter of any of the rejected claims.

It would be obvious to one skilled in the art that with the varying release profiles of the different actives, the "combined therapeutic effects" would only be accomplished if the plasma concentrations of the actives were within or "substantially coextensive" with the therapeutically effective range of the two actives given the teaching of Fanara (see discussion above). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pharmaceutical composition having combined therapeutic effects of more than one active substance, as taught by Fanara, in view of the codeine phosphate and second active substances, as taught by Jaeger, and produce the instant invention. The motivation to combine these references is provided by the composition taught by Fanara where combined therapeutic effects are obtained by means of two active substances having very different pharmacokinetic profiles.

Therefore, the rejection of 5/25/07 is maintained.

Rejection of claims 8-11, 37, 45-46 under 35 USC § 103(a)

11. Applicant's arguments, see Page 75, filed 07/31/2007, with respect to the rejection of claims 8-11, 37, 45-46 under 35 USC § 103(a) as being unpatentable over

Fanara et al. (US 6,699,502) in view of Jaeger (US 3,914,425) and further in view of Findlay et al. (US 4,650,807) have been fully considered but are not persuasive.

Applicant argues that Findlay is cited only to show that it is known in the art that certain antihistamines may be formulated together with decongestants. One of ordinary skill in the art would make the pharmaceutical composition having combined therapeutic effects of more than one active substance, as taught by Fanara, in view of the codeine phosphate and second active substances, as taught by Jaeger, and further combine it with the antihistamines formulated together with decongestants, as taught by Findlay, and produce the instant invention. The motivation to combine these references is provided by the composition taught by Fanara where combined therapeutic effects are obtained by means of two active substances having very different pharmacokinetic profiles and antihistamines and decongestants would supplement the antitussive active substances for ameliorating cough symptoms.

Therefore, the rejection of 5/25/07 is maintained.

Provisional Rejection of claims under nonstatutory obviousness type double patenting

12. Applicant's request that the provisional rejection of claims under nonstatutory obviousness type double patenting be held in abeyance is acknowledged. However until such time that allowable subject matter is decided, the provisional rejections will be maintained.

MAINTAINED REJECTIONS/OBJECTIONS:

The following are maintained rejections/objections. The rejections also include the newly added claims 99-116.

Claim Objections

13. Claim 78 is objected to because of the following informalities: The phrase "wherein the dosage form releases the at least one first morphine derivative at least one of over a different period" should be "wherein the dosage form releases the at least one first morphine derivative over a different period". Appropriate correction is required.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-3, 18-21, 78, 80, 92-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502).

The claimed invention is a pharmaceutical dosage form that contains a morphine derivative with antitussive activity in combination with at least one additional active ingredient. The dosage form releases the morphine derivative and the additional active ingredient at rates that provide pharmaceutically suitable plasma concentrations over similar periods of time. The dosage form comprises tablets, bi-layered tablets, and multi-layered tablets.

Fanara teaches a pharmaceutical composition (including a multi-layered pharmaceutical composition) for oral administration that allows the release of at least one active substance and includes a matrix (Abstract). Fanara teaches, "the release of active substances during oral administration can be controlled by means of matrix-type pharmaceutical compositions" (Col. 1, lines 14-16). The compositions "can be administered in a few daily doses, ideally in a single daily dose" (Col. 1, lines 9-13). Fanara further teaches, "it is increasingly advantageous to be able to simultaneously administer by oral route an active substance released immediately after administration, and the same or a second active substance released gradually and regularly after administration ... this makes it possible to obtain combined therapeutic effects by means of two active substances having very different pharmacokinetic profiles" (Col. 2, lines 36-50). This reference also teaches that "controlled-release pharmaceutical compositions can be used in combination with an immediate-release pharmaceutical composition for the same or for another active substance, in a single unit intended to be administered orally" (Col. 3, lines 32-37). Antihistamines, antitussives, such as codeine, morphine, and their pharmaceutically acceptable salts, along with pseudoephedrine, and phenylepherine may be included in the composition (Col. 4, lines 54-67). The pharmaceutical composition can be in the form of tablets (Col. 5, lines 18-20). The tablets can be bilayered (Col. 5, lines 48-58) or multilayered (Col. 6, lines 20-26). Example 7 of this reference discloses a double-layer tablet (with the two layers stuck to each other) containing 15mg doses of hydrocodone bitartrate (10mg of the hydrocodone

is in a controlled release layer and 5mg of the hydrocodone is in an immediate release layer (Col. 12, line 25-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pharmaceutical composition having combined therapeutic effects of more than one active substance, as suggested by Fanara, and produce the instant invention.

The pharmaceutical dosage form comprising a first drug (morphine derivative having antitussive activity) and a second drug where the dosage form provides a plasma concentration within a therapeutic range of the second drug over a period which is coextensive with at least about 70% of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug would have been obvious to one skilled in the art over Fanara. As mentioned above, Fanara teaches simultaneously administering more than one active substance and combining the therapeutic effects of active substances with different pharmacokinetic profiles (Col. 2, lines 36-50) and includes antitussives, antihistamines, codeine, and morphine as possible active substances in the composition. In order to have the combined therapeutic effects of active substances, it would have been obvious to one with ordinary skill in the art that the period of therapeutic effectiveness of the first active substance would be coextensive with the period of therapeutic effectiveness of the second active substance, especially if the two active substances are related to similar (antitussive) therapeutic activities.

Regarding instant claims 18-21, the tablet (bilayered) and comprising a matrix with the first drug and particles with the second drug would have been obvious to a person with ordinary skill in the art over the Fanara teaching of bilayered tablets and matrix.

One of ordinary skill in the art would have been motivated to do this because the pharmaceutical composition as taught by Fanara allows the release of the "active substances such that a satisfactory therapeutic effect is observed over fairly long periods, for example in only one or even two daily doses" (Col. 3, lines 22-27).

16. Claims 4-7, 15-17, 23-29, 30-36, 38-44, 47, 49-52, 72-77, 81-87 and new claims 99-111, 114-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502) as applied to claims 1-3, 18-21, 78, 80, 92-96, above, in view of Jaeger (US 3,914,425).

The teaching of Fanara is stated above.

Fanara does not expressly teach codeine phosphate as the active substance.

Jaeger teaches an antitussive codeine composition. Example 2 of this reference illustrates a three-layer "pill" or tablet containing codeine phosphate (Col. 2, lines 43-47). "An intermediate layer containing 6mg each of the two active ingredients was protected by a thin coating ... and the outer layer contained 18mg codeine phosphate". Jaeger also teaches "preparations containing codeine may additionally contain antihistamines such as triprolidine hydrochloride, decongestants such as pseudoephedrine hydrochloride, and expectorants such as glyceryl guaiacolate" (Col. 3, lines 3-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pharmaceutical composition having combined therapeutic effects of more than one active substance, as suggested by Fanara, in view of the codeine phosphate and second active substances (antihistamines, decongestants, and expectorants) as suggested by Jaeger and produce the instant invention.

Regarding instant claims 51-52, one with ordinary skill in the art would use the teachings of Fanara and Jaeger to produce tablets with multiple layers, where the multiple layers were adjacent to each other, or one layer surrounding the other.

Regarding instant claims 12-14, 47, and 73 one with ordinary skill in the art would use the teachings of Fanara and Jaeger to make a pharmaceutical composition by using drug combinations (antitussives, antihistamines, decongestants, expectorants) with drugs having different plasma half-lives in order to optimize the release of drugs over time. Drugs that are part of the immediate release would have a different plasma half-life than drugs that are part of the controlled release in order to maintain drug release for optimal therapeutic effect.

Regarding instant claims 15-17, 28-29, and 72-74, one with ordinary skill in the art would use the teachings of Fanara and Jaeger to make pharmaceutical compositions using drugs with different pharmacokinetic profiles (Fanara, Col. 2, lines 46-50). The claim limitations of periods of plasma concentration within the therapeutic range of the second drug being coextensive with at least about 80%, 90% or 95% of periods of plasma concentration within the therapeutic range of the first drug would

have been obvious over the different pharmacokinetic profiles taught by Fanara in view of the antitussive codeine composition taught by Jaeger.

Regarding instant claims 97-98, a person with ordinary skill in the art would use the teachings of Fanara and Jaeger to make a pharmaceutical dosage form with a morphine derivative as the first drug and the second drug. Furthermore, Fanara also teaches, "as regards the dose of active substance used, it depends on the effective dose and may therefore vary within very wide limits depending on the said active substance" (Col. 5, lines 1-3). A person with ordinary skill in the art would formulate the composition in order to optimize the plasma concentration of the morphine derivative so that release of the morphine derivative from the two layers does not exceed the safe limit (maximum plasma concentration of the therapeutic range) of the morphine derivative.

One of ordinary skill in the art would have been motivated to do this because the pharmaceutical composition as taught by Fanara allows the release of the "active substances such that a satisfactory therapeutic effect is observed over fairly long periods, for example in only one or even two daily doses" (Col. 3, lines 22-27). The second drugs taught by Jaeger would have been obvious to one skilled in the art as supplementing the antitussive first drugs for ameliorating cough symptoms.

17. Claims 8-11, 37, 45-46, and new claims 112-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502) as applied to claims 4-7, 15-17, 23-29, 30-36, 38-44, 47, 49-52, 72-77, 81-87, and 97-98, above, in view of Jaeger (US 3,914,425) and further in view of Findlay et al. (US 4,650,807).

The teachings of Fanara and Jaeger are stated above.

Fanara and Jaeger do not expressly teach chlorpheniramine, promethazine, and guaifenesin.

Findlay teaches antihistaminic compositions. These compositions include tablets (Col. 5, lines 33-35). Antihistamines such as pheniramines, and promethazine are disclosed (Col. 1, lines 26-28). It is also taught that, "the active compound may be formulated with a sympathomimetic agent such as decongestants pseudoephedrine or phenylpropanolamine, an antitussive such as codeine ... or an expectorant such as guaifenesin" (Col. 5, lines 9-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pharmaceutical composition with combined therapeutic effects of more than one active substance, as suggested by Fanara, in view of the codeine phosphate and second active substances (antihistamines, decongestants, and expectorants) as suggested by Jaeger and further in view of the specific antihistamines and expectorant as suggested by Findlay and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the specific active substances taught by Findlay supplement the antitussive first drugs for ameliorating cough symptoms.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-52, 72-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-13, 15-21, 25-35, 38-40, 43-50, 68, 70, 73-77 of copending Application No. 10/736,902 ('902 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '902 is promethazine and a pharmaceutically acceptable salt thereof. One with ordinary skill in the art would use various drugs that were compatible in the composition. Promethazine is an antihistamine and since an antihistamine can be a component of the instant dosage form (second drug of instant claim 5), one with ordinary skill in the art would be motivated to use it in the composition.

20. Claims 1-52, 72-73, 75-78, 83, 85-87, 92-98 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22, 24-25, 27-36, 39-40, 44-50, 69-70, 73-76, 79, 83-85, 94-99 of copending

Application No. 10/910,806 ('806 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '806 is carbetapentane and a pharmaceutically acceptable salt thereof. One with ordinary skill in the art would use various drugs that were compatible in the composition. Carbetapentane is a cough suppressant and since an expectorant or a decongestant can be a component of the instant dosage form (second drug of instant claim 5), one with ordinary skill in the art would be motivated to use a cough suppressant in the composition.

21. Claims 1-52, 72-88 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-87 of copending Application No. 10/939,351 ('351 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '351 is phenylepherine and a pharmaceutically acceptable salt thereof. One with ordinary skill in the art would use various drugs that were compatible in the composition. Phenylepherine is a decongestant and since a decongestant can be a component of the instant dosage form (second drug of instant claim 5), one with ordinary skill in the art would be motivated to use it in the composition.

22. Claims 1-52, 72-98 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-20, 25, 27-50, 68-76, and 80-84 of copending Application No. 11/012,267 ('267 hereinafter).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '267 is diphenhydramine and a pharmaceutically acceptable salt thereof. One with ordinary skill in the art would use various drugs that were compatible in the composition. Diphenhydramine is an antihistamine and since an antihistamine can be a component of the instant dosage form (second drug of instant claim 5), one with ordinary skill in the art would be motivated to use it in the composition.

23. Claims 1-8, 23, 75-77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-10, 25-26, 28-30, 32 of copending Application No. 11/115,293 ('293 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '293 is promethazine and a pharmaceutically acceptable salt thereof. One with ordinary skill in the art would use various drugs that were compatible in the composition. Promethazine is an antihistamine and since an antihistamine can be a component of the instant dosage form (second drug of instant claim 5), one with ordinary skill in the art would be motivated to use it in the composition.

24. Claims 1, 5-7, 9-18, 21-23, 28-29, 30-33, 39-42, 50-51, 72-77, and 78-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6-8, 12-13, 17-20, 21-24, 28-34, 38-41, 47-50, 60-65, 67-70, 73-74, 79-83, 86-90, 92, 95-96, 114, 117-119 of copending Application

No. 11/115,321 ('321 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '321 is an antitussive that comprises a morphine derivative. Since a morphine derivative having antitussive activity is a component of the instant dosage form (first drug of instant claim 1), one with ordinary skill in the art would be motivated to use it in the composition.

25. These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Conclusion

26. No claims are allowed.

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-

9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600